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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/395,677	09/10/99	BERGER	D P-4579

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RICHARD J RODRICK ESQ
BECTON DICKINSON AND COMPANY
1 BECTON DRIVE
FRANKLIN LAKES NJ 07417

EXAMINER	
FORMAN, B	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/395,677	Applicant(s) BERGER ET AL.	
	Examiner BJ Forman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16 and 18-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16 and 18-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to papers filed 10 July 2001 in Paper No. 16 in which claims 21 and 23 were amended. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 14 dated 10 April 2001 under 35 U.S.C. 112, first paragraph are maintained. The previous rejections under and 35 U.S.C. 103(a) are withdrawn in view of the new grounds for rejection. All of the arguments have been thoroughly reviewed but are deemed moot in view of the withdrawn rejections and new ground for rejection. New grounds for rejection are discussed.

Currently claims 13-16 and 18-32 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

First paragraph of 35 U.S.C. 112: New Matter

3. Claims 13-16 & 18-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims as amended are drawn to a method for stabilizing the structure and nucleic acids of at least one cell in a sample comprising adding to a vessel containing the sample a composition comprising a first substance having a concentration effective for precipitating or denaturing protein, comprising at least one alcohol or ketone whose concentration is less than 80% of the total composition; and a second

facilitator substance having a concentration effective for aiding in the infusion of the first substance into said at least one cell whose concentration is greater than 20% of the total composition. The claimed composition encompasses composition concentrations not disclosed in the specification i.e. a first substance of concentrations 0.001% to 79.99% and the second substance having concentrations of 20.001% to 99.99%. The specification teaches the preferred embodiment is 50% methanol/50% DMSO (page 4, lines 19-24). Additionally, the specification teaches 80% methanol/20% DMSO; 50% methanol/50% DMSO; and 100% methanol; 40% methanol + 40% ethanol/ 20% DMSO; 25% methanol + 25% ethanol/ 50% DMSO; and 80% ethanol/20%DMSO; 20% methanol/80% DMSO; 40% methanol/60% DMSO; 60% methanol/40% DMSO; 100% methanol; and 100%DMSO (Examples 4-12, pages 14-19, 21 & 23). However, the specification does not teach the broadly claimed compositions i.e. a first substance of concentrations 0.001% to 79.99% and the second substance having concentrations of 20.001% to 99.99% (e.g. 78% alcohol/ 22% DMSO). Therefore the claims, as amended, introduce new matter not disclosed in the specification as originally filed. It is suggested that the claims be amended to claim the invention as recited in the specification as originally filed.

Response to Arguments

4. Applicant argues that it would be improper and unreasonable to expect that concentrations of 0.001% to 79.99% would have to be taught to allow a statement of less than 80% to be allowed. This argument has been considered but not found persuasive because as stated above, the specification teaches a very few of the claimed compositions. Specifically, the claims are drawn to a method comprising a composition comprising a first substance of concentrations 0.001% to 79.99% and the second substance having concentrations of 20.001% to 99.99% but the specification teaches a few specific examples of the claimed compositions i.e. 80% methanol/20% DMSO; 50% methanol/50% DMSO; and 100% methanol; 40% methanol + 40% ethanol/ 20% DMSO; 25% methanol + 25% ethanol/ 50% DMSO; and 80% ethanol/20%DMSO; 20% methanol/80% DMSO; 40% methanol/60% DMSO; 60% methanol/40% DMSO; 100% methanol; and 100%DMSO (Examples 4-12, pages 14-19, 21 & 23) but the specification does not teach the enormous variety of compositions now claimed. Therefore, the claims, as amended, introduce new matter not disclosed in the specification as

originally filed. It is suggested that the claims be amended to claim the invention as recited in the specification as originally filed.

First paragraph of 35 U.S.C. 112: Written Description

5. Claims 13-16 & 18-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims, as amended, are drawn to a method for stabilizing the structure and nucleic acids of at least one cell in a sample the method comprising: adding to a vessel containing the sample a composition comprising a first substance having a concentration effective for precipitating or denaturing protein, comprising at least one alcohol or ketone whose concentration is less than 80% of the total composition; and a second facilitator substance having a concentration effective for aiding in the infusion of the first substance into said at least one cell whose concentration is greater than 20% of the total composition. The specification teaches the claimed method for stabilization of cells in a vaginal swab samples (page 7, lines 7-9 and 24-26). Additionally, the specification teaches specific cell types found in vaginal fluid i.e. *Trichomonas vaginalis*, *Gardnerella vaginalis* and *Candida albican* and the specification teaches the claimed methods stabilize the structure and nucleic acids in these cell types (pages 11-12, Examples 2 & 4-12). The specification suggests the method "could be used for other biological specimens" (page 4, lines 26-29). However, the specification does not teach the method stabilizes the structure and nucleic acids of other specimens in the very large genus of cells as claimed. The claimed cells encompasses eukaryotic cells which further encompasses plant and animal cells each of which further encompass numerous species and sub-species, prokaryotic cells which further encompasses bacteria which further encompasses numerous species not described in the specification. The specification fails to teach a representative number of the claimed species. The specification

teaches various formulations of the claimed method composition and experimental conditions using the compositions (Examples 4-12) but the specification does not teach using the claimed method with a representative number of the claimed cell species.

Additionally, the claimed composition encompasses a very large genus of compositions not disclosed or described in the specification. The claims are drawn to a first substance whose concentration is less than 80% of the total composition; and a second facilitator substance whose concentration is greater than 20% of the total composition. The claimed concentrations encompasses a very large genus of compositions wherein the first substance has a concentration ranging from 0.001% to 79.99% encompassing all minor variations between 0.001% to 79.99% and the second substance has a concentration ranging from 20.001% to 99.99% encompassing all minor variations between 20.001% to 99.99%. The specification teaches 80% methanol/20% DMSO; 50% methanol/50% DMSO; and 100% methanol; 40% methanol + 40% ethanol/ 20% DMSO; 25% methanol + 25% ethanol/ 50% DMSO; and 80% ethanol/20%DMSO; 20% methanol/80% DMSO; 40% methanol/60% DMSO; 60% methanol/40% DMSO; 100% methanol; and 100%DMSO (Examples 4-12, pages 14-19, 21 & 23). However, the claimed compositions encompass an extremely large genus of compositions not disclosed in the specification.

Therefore, because the specification does not teach a representative number of the very large genus of claimed compositions and does not teach a representative number of the large genus of claimed cell species, the specification does not teach the specification does not provide a written description of the claimed composition in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The courts have stated that the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonable conclude the inventor had possession of the claimed invention see *In re Vas-Cath*, Inc. 935F2d. 1555, 1563, 19 USPQ2d 1111,1116. It is suggested that the claims be amended to claim the

invention as described in the specification e.g. by inserting "in vaginal fluid" after "one cell" in line 2 of Claim 13.

Response to Arguments

6. Applicant argues that the inventors were in possession of the present invention and that it is unreasonable to expect that examples with different cells showing nucleic acid preservation and other examples with different cells showing structure preservation would not be enough to allow a claim to structure and nucleic acid. The argument is not found persuasive because, as stated above, the claims are drawn to a very large genus of compositions and a very large genus of cell types and because the specification teaches only a very few examples of the claimed compositions and cell types, the specification does not provide a written description of the claimed composition in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant argues that Example 11, the most preferred embodiment demonstrates RNA stability in whole blood, serum and plasma. Example 11 illustrates that RNA spotted on a dipstick remained visible in the presence of whole blood, serum and plasma samples containing one of the claimed compositions (i.e. 50% methanol/50% DMSO). Example 11 clearly illustrates that one of the claimed compositions inactivates RNase present in the whole blood, serum and plasma samples to thereby stabilizing the RNA on the dipstick, but Example 11 does not illustrate a method for stabilizing the structure or nucleic acids of at least one cell as claimed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 13, 14, 16, 20, 25-27 and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Evinger-Hodges et al. (WO 90/02204, published 8 March 1990) as taught by

Gee et al. (U.S. Patent No. 6,162,931, filed 12 April 1996) and NCBI (MeSH Browser; www.ncbi.nlm.nih.lgov:80/entrez/m...n& term+Fixatives&Lable+Browse+this+term).

Regarding Claim 13, Evinger-Hodges et al. disclose a method for stabilizing the structure and nucleic acids of at least on cell in a sample comprising (page 13, line 29-page 14, line 3): adding a composition comprising a first substance having a concentration effective for precipitating or denaturing proteins comprising at least one alcohol whose concentration is less than 80% of the composition and a second substance having a concentration effective for aiding in the infusion into said cell whose concentration is greater than 20% of the composition (i.e. 50% methanol/50% acetone); contacting the cell with said composition; incubating said cell with said composition for an effective period of time and temperature to thereby obtain a cell with stabilized structure and nucleic acids in said sample (page 6, line 25-page 7, line 4). Gee et al. teach that acetone is a facilitator substance which when accompanied by a fixative (e.g. methanol) aids infusion (Column 30, lines 54-60). Additionally, it is noted that the NCBI MeSH browser defines "fixative" as "Agents employed in the preparation of specimens for the purpose of maintaining the existing form and structure of all of the constituent elements." Therefore, the fixative of Evinger-Hodges et al. comprising 50% methanol/50% acetone stabilizes the structure and nucleic acids of a cell as claimed.

Regarding Claim 14, Evinger-Hodges et al. disclose the method wherein said alcohol is methanol (page 6, lines 25-28).

Regarding Claim 16, Evinger-Hodges et al. disclose the method wherein said first substance is one alcohol i.e. methanol (page 6, lines 25-28).

Regarding Claim 20, Evinger-Hodges et al. disclose the method wherein the first and second substances in the composition are in a ratio or 1:1 i.e. 50% methanol:50% acetone (page 6, line 27).

Regarding Claim 25, Evinger-Hodges et al. disclose the method wherein said nucleic acid is DNA (page 6, lines 1-12).

Regarding Claim 26, Evinger-Hodges et al. disclose the method wherein said nucleic acid is RNA (page 6, lines 1-12).

Regarding Claim 27, Evinger-Hodges et al. disclose the method wherein the RNA is ribosomal RNA (page 6, lines 1-12).

Regarding Claim 29, Evinger-Hodges et al. disclose the method wherein said effective temperature is room temperature (page 6, line 35-page 7, line 1).

Regarding Claim 30, Evinger-Hodges et al. disclose the method wherein said effective temperature is from about 0° C to 40° C (page 6, line 35-page 7, line 1).

Regarding Claim 31, Evinger-Hodges et al. disclose the method wherein said cell is eukaryote (page 13, lines 29-35).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 15, 18, 19, 21-24, 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evinger-Hodges et al. (WO 90/02204, published 8 March 1990) in view of Gee et al. (U.S. Patent No. 6,162,931, filed 12 April 1996).

Regarding Claim 15, Evinger-Hodges et al. disclose a method for stabilizing the structure and nucleic acids of at least on cell in a sample comprising (page 13, line 29-page 14, line 3): adding a composition comprising a first substance having a concentration effective for precipitating or denaturing proteins comprising at least one alcohol whose concentration is less

than 80% of the composition and a second substance having a concentration effective for aiding in the infusion into said cell whose concentration is greater than 20% of the composition (i.e. 50% methanol/50% acetone); contacting the cell with said composition; incubating said cell with said composition for an effective period of time and temperature to thereby obtain a cell with stabilized structure and nucleic acids in said sample (page 6, line 25-page 7, line 4). Gee et al. teach that acetone is a facilitator substance which when accompanied by a fixative (e.g. methanol) aids infusion (Column 30, lines 54-60). Additionally, it is noted that the NCBI website defines "fixative" as "Agents employed in the preparation of histologic or pathologic specimens for the purpose of maintaining the existing form and structure of all of the constituent elements." Therefore, the fixative of Evinger-Hodges et al. comprising 50% methanol/50% acetone stabilizes the structure and nucleic acids of a cell as claimed. Evinger-Hodges et al. do not teach the second substance is selected from the group consisting of dimethyl sulfoxide (DMSO), ethylene glycol and polyethylene glycol. However, Gee et al. teach a similar composition comprising; a first substance capable of precipitating or denaturing proteins comprising alcohol i.e. a fixative solution comprising methanol, and a second facilitator substance to aid in the infusion of the first substance into said at least one cell i.e. DMSO, wherein the concentrations of said first and second substances are effective to stabilize the structure and nucleic acids of said at least one cell (Column 30, lines 46-60). The courts have stated that in considering methods, it would be obvious to one of skill in the art in view of the method to "substitute one equivalent for another" and "express suggestion to substitute one equivalent for another need not be present to render such substitution obvious" (see *In re Fout*, 213 USPQ 532). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the acetone facilitator substance in the fixative of Evinger-Hodgers et al. with DMSO based on the teaching of Gee et al. wherein acetone and DMSO function equivalently in a fixative composition to facilitate transmembrane transport.

Regarding Claim 18, Evinger-Hodges et al. teach the method wherein the first substance is comprised of one alcohol (page 6, lines 25-28) but they do not teach the first substance is comprised of a first alcohol and a second alcohol or ketone. It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition comprising one alcohol taught by Evinger-Hodges et al. and based on the similar chemical and functional properties of alcohols add a second alcohol using routine experimentation to optimize experimental conditions to thereby maximize experimental results.

Regarding Claim 19, Evinger-Hodges et al. teach the method wherein the first substance is comprised of one alcohol (page 6, lines 25-28) but they do not teach a composition ratio of 2.5:2.5:5. It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition and ratio of components in the composition using routine experimentation to optimize experimental conditions to thereby maximize experimental results.

Regarding Claim 21, Evinger-Hodges et al. teach the method wherein the first substance is methanol and the second substance is acetone (page 6, lines 25-28) but they do not teach the second substance is DMSO. However, Gee et al. teach the similar composition wherein said first substance is methanol and said second substance is DMSO and they teach that DMSO and acetone function to facilitate infusion (Column 30, lines 46-56). The courts have stated with regard to chemical homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see

Dillon, 99 F.2d at 696, 16 USPQ2d at 1904). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the acetone which facilitates infusion in the composition of Evinger-Hodges et al. with the functional equivalent, DMSO, as suggested by Gee et al. based on available reagents for the expected benefit of convenience.

Regarding Claim 22, Evinger-Hodges et al. teach the method wherein the first substance is an alcohol e.g. methanol or ethanol and the second substance is acetone (page 6, lines 25-28) but they do not teach the first substance is comprised of a first and second alcohol or ketone and the second facilitator is DMSO. However, Gee et al. teach the similar composition wherein said first substance is methanol and said second substance is DMSO and they teach that DMSO and acetone function to facilitate infusion (Column 30, lines 46-56). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the acetone which facilitates infusion in the fixative composition of Evinger-Hodges et al. with the functional equivalent, DMSO, as suggested by Gee et al. based on available reagents for the expected benefit of convenience. Additionally, the courts have stated with regard to chemical homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904). It was known in the art at the time the claimed invention was made that ethanol and methanol are chemical homologs due their physical and chemical similarities. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the alcohol composition of Evinger-Hodges et al. based on their ethanol or methanol teaching and using routine experimentation add a second alcohol to the composition to thereby optimized experimental conditions and maximized experimental results for a specific cell type as taught by Evinger-Hodges et al. (page 13, lines 21-23).

Regarding Claim 23, Evinger-Hodges et al. teach the method wherein the first substance is methanol and the second substance is acetone (page 6, lines 25-28) but they do not teach the first substance is ethanol and said second substance is DMSO. It was known in the art at the time the claimed invention was made that ethanol and methanol are chemical homologs due their physical and chemical similarities. Additionally, Gee et al. teach the similar method and they teach that acetone and DMSO are functional equivalents in that they both facilitate infusion (Column 30, lines 54-56). The courts have stated with regard to chemical homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the alcohol in the composition of Evinger-Hodges et al. based on their ethanol or methanol teaching and using routine experimentation use ethanol in the composition to thereby optimized experimental conditions and maximized experimental results for a specific cell type as taught by Evinger-Hodges et al. (page 13, lines 21-23). It would have been further obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the acetone which facilitates infusion in the fixative composition of Evinger-Hodges et al. with the functional equivalent, DMSO, as suggested by Gee et al. based on available reagents for the expected benefit of convenience.

Regarding Claim 24, Evinger-Hodges et al. teach the method wherein the first substance is methanol and the second substance is acetone in a ratio of 1:1 (page 6, lines 25-28) but they do not teach the second substance is DMSO (Column 30, lines 46-56). Gee et al. teach the similar method and they teach that acetone and DMSO are functional equivalents in that they both facilitate infusion (Column 30, lines 54-56). The courts have stated with regard to chemical homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the

claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the acetone which facilitates infusion in the fixative composition of Evinger-Hodges et al. with the functional equivalent, DMSO, as suggested by Gee et al. based on available reagents for the expected benefit of convenience.

Regarding Claim 28, Evinger-Hodges et al. teach the method wherein the effective time is 1 to 180 minutes (page 6, lines 33-34) by they do not teach the time is one to four days. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the effective time taught by Evinger-Hodges et al. and using routine experimentation increase the time from three hours to one to four days (i.e. overnight or over the weekend) for the expected benefit of the convenience of overnight incubation i.e. incubation can be preformed in the absence of laboratory personnel.

Regarding Claim 32, Evinger-Hodges et al. teach the method wherein the cell specimen is any material which is composed of cells (page 11, lines 30-35) and it was known in the art at the time the claimed invention was made that microorganisms comprises cells i.e. bacterial cells, yeast cells and etc. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the composition of Evinger-Hodges et al. to microorganisms for the obvious benefit of stabilizing the nucleic acids of clinically important organisms for study and diagnostic purposes.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
August 16, 2001